510(k) Summary of Safety and Effectiveness for the

LOCI CA 19-9 (CA19-9) Flex® Reagent Cartridge

APR - 6 2011

Dimension Vista® LOCI 7 Calibrator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: k100375

B. Date of Preparation: February 11, 2010

C. Proprietary and Established Names:

LOCI CA 19-9 Flex® Reagent Cartridge

Dimension Vista® LOCI 7 Calibrator

D. Applicant:

Siemens Healthcare Diagnostics Inc.

P.O. Box 6101, Newark, DE 19714-6101

Pamela A. Jurga, Regulatory & Clinical Affairs Specialist

Office Number: (302) 631-8891 fax Number: (302) 631-6299

E. Regulatory Information:

LOCI CA 19-9 Flex® Reagent Cartridge:

1. Regulation section: 21 CFR § 866.6010 Tumor-Associated antigen immunological test system
2. Classification: Class II
3. Product Code: NIG – System, Test, Carbohydrate Antigen (CA 19-9) for Monitoring and Management of Pancreatic Cancer
4. Panel: Immunology

LOCI 7 Calibrator:

1. Regulation section: 21 CFR § 862.1150 Calibrator
2. Classification: Class II
3. Product Code: JIT – Calibrator, Secondary
4. Panel: Immunology

F. Predicate Device:

The predicate device used to demonstrate substantial equivalence to the LOCI CA19-9 Flex® Reagent Cartridge is the CA 19-9 Assay for the ADVIA Centaur® System previously cleared under k031393.

The predicate device used to demonstrate substantial equivalence to the Dimension Vista® LOCI 7 Calibrator is the ADVIA Centaur® Calibrator 9 previously cleared under k031393.

G. Device Description:

The CA19-9 method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI® technology. The LOCI® reagents include two synthetic bead reagents and a biotinylated anti-CA 19-9 monoclonal 1116-NS-19-9 antibody fragment. The first bead reagent (Chemibeads) is coated with an anti-CA 19-9 monoclonal antibody (1116-NS-19-9) and contains a chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. Sample is incubated with biotinylated antibody and Chemibeads to form bead-CA 19-9-biotinylated antibody sandwiches. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the CA 19-9 concentration in the sample when measured against a calibration curve.

The LOCI 7 calibrator is a liquid, frozen bovine serum albumin, based product containing CA 19-9 from human cell culture. The kit consists of ten vials, two vials per level (A-E), 2.0 mL per vial.

H. Intended Use:

The CA19-9 method is an *in vitro* diagnostic test for the quantitative measurement of the CA 19-9 tumor-associated antigen in human serum and (lithium heparin and EDTA plasma on the Dimension Vista® System. Measurements of CA 19-9 are indicated for the serial measurement of CA19-9 to aid in managing patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum CA 19-9 at some point in their disease process exceeding the median concentration determined for the apparently healthy cohort. CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.

The LOCI 7 CAL is an *in vitro* diagnostic product for the calibration of the Cancer Antigen 19-9 (CA 19-9) CA 19-9 method on the Dimension Vista® system.

I. Substantial Equivalence Information:

The LOCI CA 19-9 method is substantially equivalent to other CA 19-9 test systems such as the ADVIA Centaur CA 19-9 assay (k031393). The LOCI 7 calibrator is substantially equivalent to other calibrators such as the ADVIA Centaur® Calibrator 9 calibrator (k031393). The following table provides a comparison of the important similarities and differences:

Feature	LOCI CA 19-9 Flex® reagent cartridge	CA 19-9 Assay for the ADVIA Centaur System (k030393)
Intended Use	The CA19-9 method is an *in vitro* diagnostic test for the quantitative measurement of the CA 19-9 tumor-associated antigen in human serum and lithium heparin and EDTA plasma on the Dimension Vista® System. Measurements of CA 19-9 are indicated for the serial measurement of CA19-9 to aid in managing patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum CA 19-9 at some point in their disease process exceeding the median concentration determined for the apparently healthy cohort. CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.	The ADVIA Centaur CA 19-9 Assay is an *in vitro* immunoassay for the quantitative, measurement of the CA 19-9 tumor-associated antigen, in human serum, using the ADVIA Centaur and ADVIA Centaur XP systems. This assay is indicated for the serial measurement of CA 19-9 to aid in the management of patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum CA 19-9 at some point in their disease process exceeding the median concentration determined for the apparently healthy cohort. CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.

Sample Type	Serum and lithium heparin and EDTA plasma	Serum
Measuring Range	2-1000 U/mL	1.2-700 U/mL
Sample Size	4 µL	75 µL
Measurement	Chemiluminescent: Homogenous sandwich immunoassay based on LOCI® technology	Chemiluminescent: Two site sandwich immunoassay using direct chemiluminometric technology

Feature	**LOCI 7 calibrator**	**ADVIA Centaur® Calibrator 9 previously cleared under k031393**
Intended Use	The LOCI 7 CAL is an *in vitro* diagnostic product for the calibration of the Cancer Antigen 19-9 (CA19-9) method on the Dimension Vista® System	For the *in vitro* diagnostic use in calibrating ADVIA® Centaur or ACS: 180® 19-9 assays.
Matrix	Bovine serum albumin-based matrix	Bovine serum-based matrix
Preparation	Liquid: Provided ready to use.	Lyophilized.
Number of Calibrator Levels	5 levels Target Concentrations: Level 1 (CAL A): 0 U/mL Level 2 (CAL B): 30 U/mL Level 3 (CAL C): 131 U/mL Level 4 (CAL D): 525 U/mL Level 5 (CAL E): 1050 U/mL	2 levels Low High
Storage	Store at -15 to - 25 °C.	Store at 2 to 8°C.

J. Conclusion:

The LOCI CA 19-9 method is substantially equivalent to other CA 19-9 test systems such as the ADVIA Centaur CA 19-9 assay (k031393). Comparative testing described in the submission report demonstrates substantially equivalent performance.

The LOCI 7 calibrator is substantially equivalent to other calibrators such as the ADVIA Centaur® Calibrator 9 calibrator (k031393).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993

Siemens Healthcare Diagnostics.
c/o Ms. Pamela A. Jurga
Regulatory and Clinical Affairs Specialist
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Mailstop 514
Newark, DE 19714-6101

APR 06 2011

Re: k100375
Trade/Device Name: Dimension Vista® LOCI CA19-9 Flex® reagent cartridge
Dimension Vista® LOCI 7 Calibrator
Regulation Number: 21 CFR §866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: NIG, JIT
Dated: March 31, 2011
Received: April 1, 2011

Dear Ms. Jurga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): k100375

Device Name:

Dimension Vista® LOCI 7 Calibrator

Indications for Use:

The LOCI 7 CAL is an *in vitro* diagnostic product for the calibration of the Cancer Antigen 19-9 (CA19-9) method on the Dimension Vista® System.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Reena Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K k100375

Indications for Use Statement

510(k) Number (if known): k100375

Device Name:

Dimension Vista® CA 19-9 Flex® Reagent

Indications for Use:

The LOCI CA19-9 method is an *in vitro* diagnostic test for the quantitative measurement of the CA 19-9 tumor-associated antigen in human serum and lithium heparin and EDTA plasma on the Dimension Vista® System. Measurements of CA 19-9 are indicated for the serial measurement of CA19-9 to aid in managing patients diagnosed with cancers of the exocrine pancreas. The test is useful as an aid in monitoring of disease status in those patients having confirmed pancreatic cancer who have levels of serum CA 19-9 at some point in their disease process exceeding the median concentration determined for the apparently healthy cohort. CA 19-9 values must be interpreted in conjunction with all other clinical and laboratory data before a medical decision is determined.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Leena Philip
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K k100375